

NESS ET AL
Serial No. 09/889,105

REMARKS

Entry of this amendment with allowance is requested.

The specification has been amended to capitalize trademarks throughout.

Accordingly, reconsideration of the objection to the specification is requested.

Claim 1 has been amended in a way which is thought to emphasize differences over the cited art. In particular, claim 1 has been amended to specify that the active material is dispersed in a hydrated cross-linked anionic gum matrix. This is fundamentally different from the encapsulation disclosed in Michael who relies on a wall to enclose the active material. Encapsulates having a wall structure are distinct from encapsulates having a matrix structure as the applicants require. This is due to the different processes and materials used to prepare them.

A matrix is not simply a material in which something is enclosed as asserted by the Examiner. In this connection, the Examiner's attention is called to the attached paper by Clark J.P., *Food Technology*, Vol. 56, No. 11, November, 2002, which states that "in matrix encapsulation the core material is dispersed within another material". By contrast, in the process of coacervation (as disclosed in Michael) to form wall encapsulates, a soluble polymer is brought out of solution to form a shell around droplets of core material. This shell is then hardened.

Also attached is a copy of article entitled "Encapsulation: New Tools for Ingredient Delivery" by Hetherington, which gives a very useful description of how these different encapsulate forms may be visualized. Paragraph 5 of this paper states that core/shell capsules can be thought of as an M&M where the core material is the peanut and the shell is the chocolate coating. Matrix encapsulates, on the other hand, can be thought of as a sponge with the active entrapped in the voids inside the sponge, so that some of the active can be seen from the outside.

Different types of encapsulation are also described in Jacobs, I.C. and N.S. Mason, *Polymeric delivery systems, properties and applications*, Edited by El-Nokaly, M.A., D.M. Piatt, and B.A. Charpentier, American Chemical Society Symposium Series 520, ISBN 0-842-26245, pages 3-4 (1993). This includes reservoir devices or encapsulates and matrix types. Specifically, reservoir devices consist of a drug or other active agent enclosed within an inert controlling membrane. Examples would be a tube filled with the active substance, where the wall of the tube would serve as the limiting membrane, a sphere of the active

FEB 20 2004 2:07 PM FR

TO 13954#562225015# P. 16

NESS ET AL
Serial No. 09/889,105

substance coated with a film controlling the diffusion of the active substance, or a slab of the active substance closed off from the medium by a film which controls the diffusion.

Matrix devices, on the other hand, have the active material dispersed throughout the polymer and are called monolithic devices or monoliths. One can distinguish between monolithic devices in which the active ingredient is dissolved, dispersed, located in connected pores, or granular.

The system described by Michael is a reservoir device which can be simply described as a wall encapsulate. In this case, the active is surrounded by a wall of secondary material. In the applicants' system, in contrast, the active is dispersed within the crosslinked anionic gum to provide a matrix encapsulate.

Consistent with the foregoing, the applicants submit that their claims distinguish over the Michael's disclosure. Accordingly, favorable reconsideration of the Section 102(b) rejection of the applicants' claims based on Michael, with allowance, is respectfully requested.

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

By:

Paul N. Kokulis
Paul N. Kokulis
Reg. No. 16,773

Date: November 21, 2003

Customer No. 09629
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Phone: (202) 739-3000
Facsimile: (202) 739-3001
Direct: (202) 739-5455